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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,211	04/09/2001	Hideshi Fujiwake	PI07331-00009	3660

7590

04/24/2002

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EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 04/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/828,211

Applicant(s)
Fujiwake et al.

Examiner
Joyce Tung

Art Unit
1637

FILE

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *Notice to Comply with Sequence Rules*

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.
3. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. Claims 1-6 are vague and indefinite because the phrase “a plurality of types of oligonucleotides” is unclear whether the phrase means that there are plurality of oligonucleotides or the phrase means that there are various type of oligonucleotides. Clarification is required.
 - b. Claims 1-6 are vague and indefinite because the phrase “the labeled oligonucleotides” has no antecedent basis.

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- c. Claims 1-6 are vague and indefinite because the phrase “hetero and homoduplexes” has no antecedent basis. In addition, the phrase “a temperature causing difference in stability between hetero and homoduplexes” is unclear what is meant by the phrase. Does it mean that the temperature causing the denaturation for hetero differs from the temperature causing the denaturation for homoduplexes. Clarification is required.
- d. Claim 4 is vague and indefinite because of the phrase “determining an inspected site corresponding to a label having a single peak a non-mutational while determining an inspected site corresponding to a label having two peaks as mutational”. Does the phrase mean that there are two labels in which one is for non mutational and another one is for mutational. Clarification is required.
- e. Claim 6 is vague and indefinite because of the phrase “a single PCR step”. It is unclear how the language is defined in the specification.

Claim Rejections - 35 USC § 102

- 4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 5. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Oefner et al. (5,795,976).

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Oefner et al. disclose a method of detecting mutation in the base sequence of nucleic acid including:

- (A) a bonding step of hybridizing an object of analysis consisting of nucleic acid or a nucleic acid fragment including a plurality of inspected sites to be subjected to inspection of mutation in the base sequence with a plurality types of oligonucleotides having base sequence complementary to any of the inspected sites having normal base sequence and labeled to be discriminable from each other for forming duplexes (See column 4, lines 16-43).
- (B) a detection step of employing an ion pair chromatograph comprising a reversed phase column serving as a separation column and a detector capable of discriminating and detecting the labeled oligonucleotide and setting the separation column at a temperature causing difference in stability between hetero and homoduplexes included in the duplexes for analyzing the object of analysis (See column 6, lines 34-45).

The limitations of claims 3 further limit the limitations of claim 1 in which the separation column is set at the melting temperature of the heteroduplex (See column 6, lines 39-42).

Since the language is unclear how the labeled oligonucleotide is detected either through chromatography or fluorescence spectrum, the language is interpreted as the labeled oligonucleotide is detected through chromatography as taught by Oefner et al. (See column 6, lines 39-45).

Thus, the teachings of Oefner et al. anticipate the limitations of claims 1 and 3.

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 2 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oefner et al. (5,795,976) as applied to claims 1 and 3 above, and further in view Diamond et al. (6,265,557).

The teachings of Oefner et al. are set forth in section 6 above and Oefner et al. do not disclose the limitations of claims 2 and 4-6

Diamond et al. disclose an allelic-specific probe for hybridization detection of nucleic acid (See column 16, lines 51-67 to column 17, lines 1-5). The oligonucleotide probe may include PNA (peptide nucleic acid) nucleotides (See column 16, lines 29-33). The probes are

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labeled with fluorescence markers in which each specific probe is labeled with different fluorescence labels (See column 22, lines 11-21). Nucleic acid from a biological sample are amplified by PCR and then subjected to hybridization conditions and are exposed to all three labeled PNA probes. After hybridization, nucleic acid are assayed for the color and intensity of any bound probes (See column 22, lines 22-26). Diamond et al. also indicate that primers specific for different alleles are multiplexed in a single PCR reaction and the primers are distinguished from one another by fluorescent labeling (See column 23, lines 40-45).

The teachings of Diamond et al. suggest the limitations of claims 2 and 4-6.

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the teachings of Diamond et al. to modify the method of Oefner et al. by using different fluorescence labels for each specific allele and amplifying the object before the bonding step as claimed. The motivation is that by using the different labels of the probes, different alleles are detected in the same assay for convenience (See column 22, lines 12-38) and before the bonding step of hybridization, and the amplification of the nucleic acid sample increases the sensitivity of the detection. Thus, it would have been prima facies obvious to carry out the method as claimed.

Sequence Rules

8. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the

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reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

In addition, all sequences in the specification are required to have SEQ ID NO, for example, the sequences in the figures.

APPLICANT IS GIVEN THREE MONTHS FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in **ABANDONMENT** of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

9. Drawings are approved.
10. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.


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Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

April 17, 2002


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600